Rotherham Doncaster and South Humber NHS Foundation Trust

WRITTEN INSTRUCTION

Written instruction to administer inactivated influenza vaccine as part of an NHS Body* or Local Authority occupational health scheme, which may include peer to peer immunisation (2023/24)

<u>For use only by the following:</u> registered nurses, registered midwives, registered nursing associates, registered operating department practitioners, registered paramedics, registered physiotherapists and registered pharmacists.

Organisation name:	Rotherham, Doncaster and South Humber NHSFT
Date of issue:	20th September 2023
Date of review (not to exceed one year from date of issue):	August 2024
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Version ratified by:	RDaSH Medicines Management Committee (16th September 2023)

Name and signature of the registered doctor authorising occupational health vaccinators, who declare themselves to have met the training and competency requirements defined in this written instruction, to operate under this written instruction on behalf of the named organisation.**

Note in the absence of an Occupational Health Service (OHS) physician this written instruction can be signed by an organisation's medical director. The Doctor signing this written instruction on behalf of the organisation they are employed by must be working within their own competency when signing.

Name	GMC Registration Number	Job Title	Signature	Date
Dr Graeme Tosh	6100798	Executive Medical Director		20.09.2023

*** An NHS Body is defined in the Human Medicines Regulations 2012 (HMR 2012) as one of the following:**

- **the Common Services Agency**
- **a health authority**
- **a special health authority**
- **Integrated Care Board**
- **an NHS trust**
- **an NHS foundation trust**

**** Occupational health vaccinators are defined in Regulations 8 of the HMR 2012. In accordance with Regulation 8 and Schedule 17 of HMR 2012, occupational health vaccinators employed or engaged by a person operating an occupational health scheme and operating under this written instruction may be: Registered nurses, midwives and nursing associates currently registered with the Nursing and Midwifery Council (NMC); operating department practitioners, paramedics and physiotherapists registered in Part 13, 8 or 9 of the Health and Care Professions Council register; Pharmacists registered with the General Pharmaceutical Council.**

Qualifications, registration, training and competency requirements	
Qualifications and professional registration	Occupational health vaccinators, employed or engaged by a person operating an occupational health scheme, and with one or more of the following professional registrations: • Registered nurses, midwives and nursing associates registered with the Nursing and Midwifery Council (NMC). • Operating department practitioners, paramedics and physiotherapists registered in Part 13, 8 or 9 of the Health and Care Professions Council register. • Pharmacists registered with the General Pharmaceutical Council. **NO OTHER PRACTITIONERS CAN USE THIS WRITTEN INSTRUCTION**
Training and competency	All vaccinators (listed above) must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD). All vaccinators (listed above) should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. All vaccinators (listed above) must have undertaken training appropriate to deliver influenza immunisation under this written instruction as required by local policy. This should be informed by the National Minimum Standards and Core Curriculum for Immunisation and tailored to the skills and competencies required for the safe and effective delivery of influenza immunisation services, including peer to peer immunisation. All vaccinators (listed above) must be competent in the handling and storage of vaccines, and management of the cold chain. RDaSH requirements • Before giving a vaccine, the healthcare professional must be competent in the following areas of practice. This be achieved by either peer observation or by self-directed learning/e-learning via ESR. 1. Understanding the principles of immunisation under PGD. 2. Supplying and administering of vaccines 3. Storage of vaccines, including cold chain procedure 4. Understanding the principles of consent 5. Taking a medical history to ascertain if client is able to have the vaccine. 6. Providing advice on the different types of vaccination. 7. Documentation of the administration. (see Records on page 10) 8. Anaphylaxis and resuscitation (annual update required) 9. Safe disposal of sharps and clinical waste 10. Indications, contraindications and adverse reactions to the vaccine,
Competency assessment	Where vaccinating is not part of the HCPs core role they must have completed the Flu Vaccinator Competency Assessment Tool, this to be signed by their clinical manager and filed in their personnel file.

	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097794/UKHSA-flu-immunisation-training-recommendations-2022-to-2023-appendix-C.pdf All vaccinators (listed above) operating under this written instruction are personally responsible for ensuring they remain up to date with the use of the vaccine/s included. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the Written Instruction and further training provided as required.

Clinical criteria	
Clinical condition or situation to which this written instruction applies	Inactivated influenza vaccine is indicated for the immunisation of staff for the prevention of influenza. *Note: Staff refers to staff of the authorising organisation or staff members of another organisation the authorising organisation is commissioned to provide this vaccination service to.*
Criteria for inclusion	Inactivated influenza vaccine should be offered to the following staff: • Employees aged 18 years and over including those in clinical at-risk groups. • Employees aged 16-17 years **not** in a clinical at-risk group. • All contracted and commissioned personnel involved in the delivery of services commissioned from RDaSH (these will include, but not exclusively, site workers, hospitality workers, volunteers, students and sub-contracted staff)
Criteria for exclusion	Individuals for whom no valid consent has been received (for further information on consent see Chapter 2 of 'The Green Book'). Individuals who: • aged under 16 years of age • employees aged 16-17 years in a clinical at-risk group – advise to attend their GP surgery to be immunised with LAIV. • have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process[1] (other than ovalbumin – see Cautions). • have received a dose of influenza vaccine for the current season • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken	**Increased bleeding risk:** • Individuals with a bleeding disorder may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume

[1] Residues from the manufacturing process may include beta-propiolactone, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, hydrocortisone, kanamycin, neomycin, octoxinol-9, octylphenol ethoxylate, polysorbate 80, sodium deoxycholate. Check the specific vaccine product SPC for details.

	intramuscular injections can be administered with reasonable safety by this route. • If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. • Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection. **Individuals with a severe anaphylaxis to egg** -which has previously required intensive care can be immunised in any setting using an egg-free vaccine, for instance QIVc or QIVr. Individuals with less severe egg allergy can be immunised in any setting using an egg-free vaccine or an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms for 0.5 ml dose). For details of the influenza vaccines available for the 2023 to 2024 season and their ovalbumin content see All influenza vaccines marketed in the UK for the 2023 to 2024 season. **Syncope (fainting)** can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Because of the absence of data on co-administration of Shingrix® vaccine with adjuvanted influenza vaccine, administration should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. Where individuals require rapid protection or are considered likely to be lost to follow up, administration at an interval of less than 7 days, or co-administration may be considered.
Action to be taken if the client is excluded	Where a client falls in the 'high risk group' and are unable to receive a vaccination under this written instruction, they should be referred to their GP In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed. Document the reason for exclusion and any action taken in the individual's Occupational Health records so that the staff ESR can be updated as appropriate.
Action to be taken if the declines treatment	Advise the individual about the protective effects of the vaccine, the risks of infection to themselves, their families and the organisation's service users and potential complications if not immunised. Advise how future immunisation may be accessed if they subsequently decide to receive the inactivated influenza vaccine. If the patient wishes to be vaccinated with non QIVc vaccine they should be advised to contact their own GP Document, advice given and the decision reached.

Arrangements for referral for medical advice	Where a patient is unable to be vaccinated, however they fall within a high risk group and wish to vaccinated; they should be advised to contact their own GP to make arrangements

Description of treatment	
Name, strength & formulation of drug	Inactivated influenza vaccine suspension in a pre-filled syringe, including: • adjuvanted quadrivalent influenza vaccine (aQIV) • recombinant quadrivalent influenza vaccine (QIVr) • cell-based quadrivalent influenza vaccine (QIVc) • egg-grown quadrivalent influenza vaccine (QIVe) **Summary table of which influenza vaccines to offer (by age)** Some influenza vaccines are restricted for use in particular age groups. The SPC for individual products should always be referred to.

16-17 year olds NOT in a clinical at-risk group	Offer QIVc If QIVc is not available, offer QIVe.
18 years to under 65 years (including those in a clinical at- risk group)	Offer QIVc or QIVr. If QIVc or QIVr are not available, offer QIVe.
65 years and over[2,3]	Offer aQIV or QIVr. If aQIV or QIVr is not available, offer QIVc. For those who become 65 years of age before 31 March 2024, aQIV may be offered off-label. • aQIV or QIVr are the first line vaccines recommended for people aged 65 and over (or turning 65 years by 31 March 2024). If not available in OHS, the OH provider should advise that the individual can have these from a GP or community pharmacy if they wish. If QIVc is available via OHS this is the acceptable second-line vaccine for this age group and can be offered if the individual does not wish to attend a GP or community pharmacy for vaccination with aQIV or QIVr . • If the OHS provider has only QIVe available, they should recommend that health and social care workers aged 65 years and over go to their GP or community pharmacy for vaccination with one of the JCVI-recommended products.

[2] Including those becoming age 65 years by 31 March 2024
[3] JCVI recommended use of QIV-HD in this age group but this is not currently available on the UK market.

Legal category	Prescription only medicine (POM).
Black triangle▼	QIVc, QIVr and aQIV products are black triangle. The QIVe vaccines are no longer designated as black triangle. This information was accurate at the time of writing. See product SPCs for indication of current black triangle status.
Off-label use	Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this protocol, unless permitted off-label administration is detailed above. Refer to products' SPCs, available from the electronic medicines compendium website, and All influenza vaccines marketed in the UK for the 2023 to 2024 season for more information. The aQIV vaccine is licensed for administration to individuals aged 65 years and over. It may be administered under this written instruction to those aged 64 years and turning 65 years of age by 31 March 2024 in accordance with the recommendations for the national influenza immunisation programme for the 2023 to 2024 season (see the annual flu letter). Vaccines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this protocol.
Route / method of administration /vaccine preparation	• Vaccines all supplied in a single (0.5ml) dose pre-filled syringe. • Administer by intramuscular (IM) injection, preferably into deltoid muscle region of the upper arm. • Influenza vaccines licensed for both intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. **Note:** QIVc, QIVr and aQIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this written instruction. • Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. • Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other /treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or /treatment is administered. A fine needle

	(23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual should be informed about the risk of haematoma from the injection. • When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. If aQIV needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs. • Shake vaccine suspensions gently before administration • Inspect the vaccine visually prior to administration for any foreign particulate matter or discolouration to and ensure appearance is consistent with the description in the vaccine product's SPC. • The SPCs provide further guidance on administration and are available from the electronic medicines compendium website www.medicines.org.uk
Dose and frequency of administration	Single 0.5ml dose for the current annual flu season (1 September 2023 to 31 March 2024).
Storage	Store at +2°C to +8°C. Do not freeze. Store in original packaging in order to protect from light. In the event of an inadvertent or unavoidable deviation of these conditions all vaccines that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance and contact the Trust pharmacy team for further advice. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and NHSE guidance in (HTM 07-01): Management and disposal of healthcare waste
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Inactivated influenza vaccine may usually be given at the same time as other vaccines (see Route and method of administration). Where co-administration with another vaccine does occur, individuals should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. A detailed list of drug interactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website.

Identification & management of adverse reactions	Pain, swelling or redness at the injection site, low-grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms after intramuscular vaccination. A small painless nodule (induration) may also form at the injection site. These symptoms usually disappear within 1 to 2 days without treatment. Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur. A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines. The frequency of injection site pain and systemic reactions may be higher in individuals vaccinated concomitantly with inactivated influenza vaccine and pneumococcal polysaccharide vaccine (PPV23) compared to vaccination with influenza vaccine alone and similar to that observed with PPV23 vaccination alone. Influenza vaccine and PPV23 may be administered at the same visit. A detailed list of adverse reactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website.
Management of and reporting procedure for adverse reactions	Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. QIVc, QIVr and aQIV are black triangle vaccines. Therefore, any suspected adverse reactions should be reported via the Yellow Card Scheme. Any adverse reaction to a vaccine should be documented in the individual's occupational health record and the individual's GP should be informed.
Written information to be given to client	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For information leaflets in accessible formats and alternative languages, please visit https://www.healthpublications.gov.uk/.
client advice / follow up treatment	Individuals should be advised regarding adverse reactions to vaccination and reassured that the inactivated vaccine cannot cause influenza. However, the vaccine will not provide protection for about 14 days and does not protect against other respiratory viruses that often circulate during the flu season. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the influenza vaccination of their household contacts. Inform the individual of possible side effects and their management. The individual should be advised when to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme When applicable, advise the individual when to return for vaccination. Individuals in a clinical risk group recommended seasonal influenza vaccine should be encouraged to inform their GP (and midwife if relevant) once they have received influenza vaccine for the current season so their medical records (and maternity records if relevant) can be updated accordingly. Individuals who decline immunisation from their OHS provider and who are immunised elsewhere should be encouraged to inform their employer of their

	immunisation status as per local policy. Resources to share with clients are available at: https://www.gov.uk/government/collections/annual-flu-programme
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. Individuals with learning disabilities may require reasonable adjustments to support vaccination (see Flu vaccinations for people with learning disabilities). A PSD may be required. The licensed ages for the 2023 to 2024 season influenza vaccines are: • QIVe licensed from 6 months of age • QIVc licensed from 2 years of age • QIVr licensed from 18 years of age • aQIV licensed from 65 years of age (see Off-label section)
Records	Record in line with local procedure: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • administered under written instruction Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. As a wide variety of influenza vaccines are available on the UK market each year, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations given within Occupational Health settings are recorded according to OH principles and ethics and in a timely manner. Local policy should be followed to encourage information sharing with the individual's General Practice where the individual would be eligible for immunisation under the national influenza programme to allow appropriate clinical follow up, improve data capture of vaccination status and to avoid duplicate vaccination. A record of all individuals receiving treatment under this written instruction should also be kept for audit purposes in accordance with local policy.

Key references

Inactivated influenza vaccination

- Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 21 September 2022. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Collection: Annual Flu Programme. Updated 9 May 2023 https://www.gov.uk/government/collections/annual-flu-programme
- The national flu immunisation programme plan 2023 to 2024: supporting letter. Published 25 May 2023. https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan
- All influenza vaccines marketed in the UK for the 2023 to 2024 season https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk
- Live attenuated influenza vaccine (LAIV) PGD https://www.gov.uk/government/publications/influenza-vaccine-fluenz-tetra-patient-group-direction-pgd-template
- Summary of Product Characteristics www.medicines.org.uk
- Flu immunisation training recommendations. Updated 12 August 2022 https://www.gov.uk/government/publications/flu-immunisation-training-recommendations
- Flu Vaccinations: Supporting people with learning disabilities. Updated 25 September 2018. https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities
- The national influenza immunisation programme - Information for healthcare practitioners

  https://www.gov.uk/government/publications/flu-vaccination-programme-information-for-healthcare-practitioners

General

- NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/
- Immunisation Against Infectious Disease: The Green Book. Chapter 2. Updated 18 June 2021. https://www.gov.uk/government/publications/consent-the-green-book-chapter-2
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018

  https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017.

  https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources
- Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them
- UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation
- Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

Vaccinator authorisation sheet

Example – other recording forms, including electronic may be used in line with local policies

Details of the approved vaccinator working for Rotherham, Doncaster and South Humber NHSFT who have completed the required training and been assessed as competent (as detailed in Section 2 and confirmed by line manager/clinical supervisor signing below) who are authorised and willing to administer inactivated influenza vaccine in accordance with this written instruction as part of the named organisation's occupational health scheme, which may include peer to peer immunisation:**

Name	Profession and Professional Registration Number	Signature	Date	Clinical Supervisor/Line manager name	Clinical supervisor/line manager signature	Date